

Notice of Allowability

Application No.

10/524,993

Applicant(s)

ANTONCIC ET AL.

Examiner

Art Unit

Andrew B. Freistein

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to After Final Amendment filed 5/15/2007.
2. ☒ The allowed claim(s) is/are 31 and 33-36 (now 1-5).
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

The After Final Amendment filed 5/15/2007 was entered. Claims 29, 31, 33-37 and 41-43 are pending. Claims 1-28, 30, 32, 38-40 and 44-50 were cancelled.

Restriction Requirement

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. **Claims 29, 31 and 33-36** drawn to a potassium salt of losartan in crystal Form X, classified in class 548, subclass 252.
- II. **Claims 37 and 41-43**, drawn to a pharmaceutical composition comprising a losartan in crystal Form X, classified in class 514, subclass 381.

The above groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct products. Invention I is a drawn to potassium salt of losartan in crystal Form X. Invention II is drawn to a pharmaceutical composition comprising a potassium salt of losartan in crystal Form X. A serious burden is imposed on the examiner to perform a complete search of the defined areas. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of the application.

During a telephone conversation with Attorney John D. Thallemer, Esq. on May 24, 2007 a provisional election was made without traverse to prosecute the invention of Group I, claims 29, 31 and 33-36. Group II, claims 37 and 41-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29, 31, 33-37 and 41-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Reddy et al., US 2004/0097568 A1.

As a result of the submission of the English-language translations of the five Slovenia patent applications, the Reddy et al. reference is no longer prior art and the rejection is withdrawn.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given during a telephone interview with Attorney John D. Thallemer, Esq. on May 24, 2007.

This application has been amended as follows:

1. Cancel claims 29, 37 and 41-43.

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2. In claim 31, after, "A potassium salt of losartan in crystal Form X" , delete "according to claim 29 characterized by a powder X-ray diffraction pattern essentially as depicted in Figure 31" , and insert --characterized by a powder X-ray diffraction pattern essentially as depicted in Figure 31 and having a melting point of about 230°C to about 237°C--.
3. In claim 33, delete, "Claim 29" and insert --Claim 31--.
4. In claim 34, delete, "Claim 29" and insert --Claim 31--.
5. In claim 35, after, "A potassium salt of losartan in crystal Form X characterized by a powder X-ray diffraction pattern" , insert --characterized by a powder X-ray diffraction pattern essentially as depicted in Figure 31,--.
6. In claim 36, delete, "Claim 29" and insert --Claim 31--.

Reasons For Allowance

The instant invention is a potassium salt of losartan in crystal form X. The closest relevant art is Reddy et al., US 2004/0097568 A1. The instant invention is patentably distinct from the closest art, because the melting point range of the instant potassium salt of losartan in crystal form X is about 230°C to about 237°C and the potassium salt of losartan in crystal form III identified in Reddy et al. is about 254°C to about 260°C.

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Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew B. Freistein whose telephone number is (571) 272-8515. The examiner can normally be reached Monday-Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

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Date: May 24, 2007